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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,922	07/09/2001	Amanda Johanne Kiliaan	BO 44633	5229

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 08/08/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/899,922	KILIAAN ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's Request for Continued Examination filed May 27, 2003 has been received and entered into the case. Claim 41 has been added, claims 26 – 41 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 41 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide support for the recitation of "gamma-3" and "gamma-6" fatty acids as originally filed.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 26 – 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 and its dependants are drawn to a method for treating depression, however are rendered vague and indefinite because step b requires a specific ratio between phospholipids, however fails to recite such a ratio. The claim merely provides an amount by weight without providing a ratio relative to the required phospholipids.

Claim 34 is rendered vague and indefinite because the claim requires a ratio of zinc to copper, however by reciting "between" it is unclear what the ratio must be. The claim appears to require a ratio of zinc to copper of 5:12, however it is unclear what may fall "between" such a ratio.

Claim 41 is rendered vague and indefinite for reciting "gamma" because it is unclear what this phrase intends to convey, as it is not adequately defined by the claim language or specification.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 26, 30, 32, 35 – 36, 38 and 41 arerejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, Maggioni (1990) and Hibino (JP 63208524 A).

Applicant claims a method for treating and/or preventing depression and depression related disorders comprising orally administering a composition comprising (a) long chain polyunsaturated fatty acids comprising omega-3 and omega-6 fatty acids in an amount of at least 350 mg/day, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine in a ratio of 0.5 – 20; and (c) at least one compound selected from folate, vitamin B12, B6, magnesium, zinc. The omega-3 fatty acids are selected from eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) and the omega-6 fatty acids are selected from arachidonic acid (ARA) and dihomogamma linolenic acid (DGLA). The (c) portion contains both folate and vitamin B6; and the composition further comprises at least one of carnitine, vitamin B1, B5, coenzyme Q10; at least one of vitamin C, E, lipoic acid, selenium salt or carotenoids; and vitamin D. Applicant additionally claims a method for treating and/or preventing depression and depression related

disorders comprising orally administering a composition comprising (a) long chain polyunsaturated fatty acids comprising omega-3 and omega-6 fatty acids in an amount of at least 350 mg/day, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and (c) at least one compound selected from folate, vitamin B12, B6, magnesium, zinc.

Horrobin teaches compositions and methods for treating depression and anxiety, the compositions comprising DHA (p.3,4), ascorbic acid (vitamin C), vitamin E, beta carotene, selenium, zinc, and vitamin B6 (p.5,7, claims). The composition may further comprise EPA, DGLA, and AA, (p.6). Specifically, dosages of at least 350 mg DHA are combined with 250 – 2000 mg of the other named fatty acids (p.6). Examples further include vitamins of the B group, vitamin D, folic acid (folate), magnesium, and lipoic acid (examples).

Maggioni teaches phosphatidylserine for treating depression and symptoms thereof (abstract).

Hibino teaches phosphatidylcholine is useful for treating depression (abstract).

The above references do not teach a composition comprising all of the combined ingredients. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine each of the claimed ingredients together with a reasonable expectation for successfully treating depression. Although the references do not teach the specific amounts or ratios as claimed, it would have been well within the purview of one of ordinary skill in the art to

optimize such amounts and/or ratios as a matter of routine experimentation. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

8. Claims 26 – 27, 29 – 20, 32 – 33, 35 – 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, Maggioni, Hibino and Fugh-Berman (1999).

Applicant claims a method for treating and/or preventing depression and depression related disorders comprising orally administering a composition comprising (a) long chain polyunsaturated fatty acids comprising omega-3 and omega-6 fatty acids in an amount of at least 350 mg/day, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine in a ratio of 0.5 – 20; and (c) at least one compound selected from folate, vitamin B12, B6, magnesium, zinc. The composition further comprises hypericin or an extract of Withania somnifera; tryptophan or a protein containing tryptophan; at least one of SAMe, choline, betaine or copper; at least one of carnitine, vitamin B1, B5, coenzyme Q10; at least one of vitamin C, E, lipoic acid, selenium salt or carotenoids; ginkgo biloba extract; or vitamin D. The omega-3 fatty acids are selected from eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) and the omega-6 fatty acids are selected from arachidonic acid (ARA) and dihomogamma linolenic acid (DGLA). The (c) portion contains both folate and vitamin B6. Applicant additionally claims a method for treating

and/or preventing depression and depression related disorders comprising orally administering a composition comprising (a) long chain polyunsaturated fatty acids comprising omega-3 and omega-6 fatty acids in an amount of at least 350 mg/day, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and (c) at least one compound selected from folate, vitamin B12, B6, magnesium, zinc.

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Maggioni teaches phosphatidylserine for treating depression and symptoms thereof (abstract).

Hibino teaches phosphatidylcholine is useful for treating depression (abstract).

Fugh-Berman teaches St. John's Wort, or hypericine (p.713), ginkgo biloba (p.715-16), vitamin B12, folate (p.721), SAMe, and tryptophan (p.722) improve depression and symptoms thereof.

The above references do not teach a composition comprising all of the combined ingredients. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose.

Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine each of the claimed ingredients together with a reasonable expectation for successfully treating depression. Although the references do not teach the specific amounts or ratios as claimed, it would have been well within the purview of one of ordinary skill in the art to optimize such amounts and/or ratios as a matter of routine experimentation. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

9. Claims 26, 29, 30, 32 – 36, 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, Maggioni, Hibino and Pollack.

Applicant claims a method for treating and/or preventing depression and depression related disorders comprising orally administering a composition comprising (a) long chain polyunsaturated fatty acids comprising omega-3 and omega-6 fatty acids in an amount of at least 350 mg/day, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine in a ratio of 0.5 – 20; and (c) at least one compound selected from folate, vitamin B12, B6, magnesium, zinc. The composition further comprises tryptophan or a protein containing tryptophan; at least one of SAMe, choline, betaine or copper; zinc and copper in weight ratio between 5 – 12; at least one of carnitine, vitamin B1, B5, coenzyme Q10; at least one of vitamin C, E, lipoic acid, selenium salt

or carotenoids; or vitamin D. The omega-3 fatty acids are selected from eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) and the omega-6 fatty acids are selected from arachidonic acid (ARA) and dihomogamma linolenic acid (DGLA). The (c) portion contains both folate and vitamin B6. Applicant additionally claims a method for treating and/or preventing depression and depression related disorders comprising orally administering a composition comprising (a) long chain polyunsaturated fatty acids comprising omega-3 and omega-6 fatty acids in an amount of at least 350 mg/day, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and (c) at least one compound selected from folate, vitamin B12, B6, magnesium, zinc.

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Maggioni teaches phosphatidylserine for treating depression and symptoms thereof (abstract).

Hibino teaches phosphatidylcholine is useful for treating depression (abstract).

Pollack teaches methods for treating depression comprising administering compositions comprising L-tryptophan, B6 (pyridoxine), vitamin C (ascorbic acid), copper and magnesium (abstract, claims 8-14).

The above references do not teach a composition comprising all of the combined ingredients. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine each of the claimed ingredients together with a reasonable expectation for successfully treating depression. Although the references do not teach the specific amounts or ratios as claimed, it would have been well within the purview of one of ordinary skill in the art to optimize such amounts and/or ratios as a matter of routine experimentation. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

10. Claims 26, 30, 32, 35 – 36, 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, Maggioni, Hibino and Takeda.

Applicant claims a method for treating and/or preventing depression and depression related disorders comprising orally administering a composition comprising (a) long chain polyunsaturated fatty acids comprising omega-3 and omega-6 fatty acids in an amount of at least 350 mg/day, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine in a ratio of 0.5 – 20;

and (c) at least one compound selected from folate, vitamin B12, B6, magnesium, zinc. The omega-3 fatty acids are selected from eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) and the omega-6 fatty acids are selected from arachidonic acid (ARA) and dihomogamma linolenic acid (DGLA). The (c) portion contains both folate and vitamin B6. The composition further comprises at least one of carnitine, vitamin B1, B5, coenzyme Q10; at least one of vitamin C, E, lipoic acid, selenium salt or carotenoids; or vitamin D. Applicant additionally claims a method for treating and/or preventing depression and depression related disorders comprising orally administering a composition comprising (a) long chain polyunsaturated fatty acids comprising omega-3 and omega-6 fatty acids in an amount of at least 350 mg/day, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and (c) at least one compound selected from folate, vitamin B12, B6, magnesium, zinc.

Horrobin teaches compositions and methods for treating depression and anxiety, the compositions comprising DHA (p.3,4), ascorbic acid (vitamin C), vitamin E, beta carotene, selenium, zinc, and vitamin B6 (p.5,7, claims). The composition may further comprise EPA, DGLA, and AA, (p.6). Specifically, dosages of at least 350 mg DHA are combined with 250 – 2000 mg of the other named fatty acids (p.6). Examples further include vitamins of the B group, vitamin D, folic acid (folate), magnesium, and lipoic acid (examples).

Maggioni teaches phosphatidylserine for treating depression and symptoms thereof (abstract).

Hibino teaches phosphatidylcholine is useful for treating depression (abstract).

Takeda teaches compositions for treating depression comprising carnitine and vitamin B1 (abstract).

The above references do not teach a composition comprising all of the combined ingredients. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine each of the claimed ingredients together with a reasonable expectation for successfully treating depression. Although the references do not teach the specific amounts or ratios as claimed, it would have been well within the purview of one of ordinary skill in the art to optimize such amounts and/or ratios as a matter of routine experimentation. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant argues that the references do not teach the claimed ratios of phospholipids and that there is no motivation to combine the references.

However these arguments fail to persuade because as stated above, each of the claimed ingredients were well known in the art to treat depression, as evidenced by the cited references. Regarding the ratio, it is unclear what ratio is required by the claims. Further, it is noted that such a ratio does not appear to impart unexpected advantages or results to the claimed composition. Absence of evidence to the contrary, the composition of the method appears to be an obvious combination of ingredients all known and used to treat depression. Moreover, without clear, specific ratios of phospholipids and unexpected advantages, the method s rendered obvious over the art cited above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
August 6, 2003

LEON B. LANKFORD, JR.
PRIMARY EXAMINER